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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 20040408

Application Number: 09/425,742
Filing Date: October 22, 1999
Appellant(s): KRAEMER ET AL.

MAILED

APR 20 2004
GROUP

Jeremy M. Stipkala
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/15/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct, as pertaining to the first paragraph. The After Final Amendment is not being entered. Thus, claims 1-23 and 28-38 are pending and appealed, and claims 3, 9, and 30-38 have been withdrawn from consideration as being directed to non-elected subject matter.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The After Final Amendment to the claims, Appendix B, is not being entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-29 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix A to the brief is correct.

(9) Prior Art of Record

| | | |
|-------------|---------------|---------|
| 5,558,859 | Cretois | 9/1996 |
| 6,162,444 | Dubois | 12/2000 |
| 5,916,910 | Lai | 6/1999 |
| 6,652,330 | Ismail | 7/1996 |
| WO 92/21317 | Galey | 12/1992 |
| WO 91/19701 | Dumats et al. | 12/1991 |

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444).

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The instant invention is directed toward a composition comprising a film-forming agent, a physiologically tolerated solvent, a plasticizer, and a generic phenylimidzolidone compounds, processes for making the composition, and processes for using the composition.

Cretois teaches compositions for the treatment and protection of the exoskeletal parts, such as hair and skin, comprising in a cosmetically acceptable medium, at least one ceramide and/or glycosphingolipid and at least one vinylpyrrolidone polymer. Polyoxyethylenated carboxylic ether acids are disclosed as anionic surfactants that are added to the composition. Water and alcohols, such as ethanol and isopropanol, and combinations thereof are disclosed as cosmetically acceptable mediums. Antiseborrheic agents are disclosed as additives.

Exemplified is a hair care composition comprising Luviquat FC 905 (plasticizer, copolymer of vinylimidazolium methochloride and vinyl pyrrolidone) and Cremophor RH 410 (film forming agent, polyethoxylated hydrogenated castor oil). The reference lacks instant formula (I) and 5-alpha-reductase inhibitors. See Col. 1, line 6-Col. 2, line 11; Col. 4, line 43-Col. 12, line 16.

Dubois teaches topical cosmetic or pharmaceutical compositions containing a dermatologically effective amount of at least one liposome containing a compound of formula (I), wherein the compound of formula (I) is synonymous to the compound of formula (I) of the instant claims. Gel, cream, milk, balm, and lotion forms of the composition are disclosed. The liposomes are disclosed as being comprised of sphingolipids (ceramides). 5-alpha reductase inhibitors such as 1,1-dimethylethyl-3-oxo-4-aza-androstene-17 carboxamide and Minoxidil (6-amino-4-piperidino-1,2-dihydro-1-hydroxy-2-iminopyrimidine) are disclosed as additives. The composition is disclosed for treating seborrhea. See Col. 1, line 24-Col. 7, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the liposome containing formula (I) of Dubois into the composition of Cretois because a) Dubois and Cretois are both directed to topical cosmetic compositions; b) Cretois teaches the addition of antiseborrhoeic agents to his composition and the compound of formula (I) is an antiseborrhoeic agent that is encapsulated in a liposome such that the concentration of the active agent in the sebaceous is higher and longer-lasting in the epidermis and dermis, minimizing the passage of the active agent into the blood circulation; c) Cretois teaches ceramides as an essential ingredient of his compositions and the liposomes of Dubois are comprised of ceramides; thus, one of skill in the art would be motivated to add the liposomes containing formula (I) of Dubois into the composition of Cretois because of the expectation of achieving an anti-seborrhoeic composition that is more effective and longer lasting, and which does not result in adverse side-effects as a result of seeping into the circulatory system.

Note: Regarding the limitation “wherein said compound of formula I is released from the film formed by application of said composition to a skin surface”, the Examiner respectfully points out that this limitation is a property of the composition and its constituents. Thus, the same composition with the same constituents will have the same property.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois and Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of Lai (5,916,910).

Cretois and Dubois are applied as discussed above. The reference lacks angiotensin converting enzyme inhibitors.

Lai teaches conjugates of dithiocarbamates with pharmacologically active agents, wherein dithiocarbamates are disclosed as reducing cutaneous irritation and alopecia. Captopril,

fosinopril, felopdipine, nicardipine, and nifedipine are disclosed as pharmacologically active agents. See Col. 3, lines 49-51; Col. 8, lines 51-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the captopril of Lai to the composition of the combined references because the combined references and Lai are both directed toward compositions comprising minoxidil that treat alopecia, and Lai teaches captopril and minoxidil as combinable; thus, one of skill in the art would be motivated to add captopril to the composition of the combined references because of the expectation treating alopecia and hypertension.

Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of Ismail (5,541,220).

Cretois and Dubois are applied as discussed above. The reference lacks methylxanthine compounds.

Ismail teach agents for the treatment and protection of the skin. Exemplified is a capsule that can treat alopecia comprising pentoxifyllin, vitamin E, and other ingredients. See Col. 8, example 24.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add pentoxifyllin to the composition of the combined references because Ismail and the combined references are directed to treating alopecia and Ismail teach pentoxifylline as increasing blood circulation; thus, one of skill in the art would be motivated to add pentoxifylline to the composition of the combined references because of the expectation of circulating the active agents of the composition through the body.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of WO 92/21317.

Cretois and Dubois are applied as discussed above. The reference lacks 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide.

WO '317 teaches compositions containing a pyridine-1-oxide of formula (I) for combating hair loss and inducing/stimulating hair growth. Specifically disclosed is 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide to the composition of the combined references because WO '317 and are all directed toward combating hair loss; thus, one of skill in the art would be motivated to add 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide to the composition of the combined references because of the expectation of further combating hair loss.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of WO 91/19701.

Cretois and Dubois are applied as discussed above. The reference lacks preferred pyridine-1-oxides and 2,6-diamino-1,3,5-triazine compounds.

WO '701 teaches triazines of formula (I) for the prevention and treatment of hair loss. Specifically disclosed are 2,6-diamino-4-piperidinopyridine and 2,6-diamino-4-butoxy-1,3,5-triazine 1-oxide. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the 2,6-dimaino-4-piperidinopyridine to the composition of the combined references because WO '701 and are all directed toward combating hair loss; thus, one of skill in the art would be motivated to add 2,6-dimaino-4-piperidinopyridine to the composition of the combined references because of the expectation of further combating hair loss.

(11) Response to Argument

*4/10/04
JW*
~~Appellant's~~
~~Applicant's~~ argument that claim 10 is definite, is persuasive. As pointed out by ~~Appellant~~
~~Applicant~~ in MPEP 2173.05(h), double inclusion is permitted, so long as it does not render the claim indefinite or result in undue multiplicity. Thus, the rejection of claim 10 under 35 USC 112 is hereby withdrawn.

*4/10/04
JW*
~~Appellant~~
~~Applicant~~ argues that the Examiner has not considered the invention as a whole, and that “ ‘compound of formula I is released from the film formed by application of said composition to a skin surface.’ The phrase, taken as a whole provides a difference from compositions that do not release the compound of formula I under the same conditions. Application of a claimed compositions to the skin is not a ‘mere recitation of an intended use,’ it is a necessary use”. This argument is not persuasive. The Examiner respectfully points out that since the combination of references teaches a composition comprising the same components, the composition of the combined references meets the limitation, “wherein said compound of formula I is released from the film formed”. However, the Examiner additionally, respectfully points out that the intended use of the composition claims, i.e. the recitation of “application of said composition to a skin surface”, is not given patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

4/104
2W
Appellant
Applicant argues, "The proposed combination lacks motivation because Cretois and Dubois treat different tissues of the body". This argument is not persuasive. It is respectfully pointed out that Cretois and Dubois are both directed toward cosmetic compositions that are applied to keratinous surfaces, wherein the skin is a keratinous surface.

4/104
2W
Appellant
Applicant argues, "Cretois teaches hair, eyelash, and nail compositions, and exemplifies hair styling mousses and mascaras-all compositions for treating keratinous tissue. . .Dubois teaches skin compositions useful for treating cancers and skin afflictions-that is, compositions for treating dermal tissues". This argument is not persuasive. It is respectfully pointed out that Cretois is directed toward the treatment of keratinous exoskeletal parts, wherein the outer layer of skin is keratinous. Regarding the exemplifications of Cretois, it is respectfully pointed out that a reference in a 103 rejection is not limited to its preferred embodiments or exemplifications, but is considered as a whole for what it teaches to those of ordinary skill in the art. Thus, Cretois and Dubois are both directed toward application of cosmetic compositions to the skin.

4/104
2W
Appellant
Applicant additionally argues, "the Examiner offers no evidence that treating hair will treat hirsutism, androgenic alopecia, or hyperpilosity. . .The leap from Dubois' treatment of hair-growth related conditions to actual treatment of the hair cannot be made. Thus, the Examiner's statement, 'Dubois does teach applying his compositions to the hair is incorrect'. This argument

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4/04
JW

is not persuasive. The Examiner respectfully directs ~~Applicant~~^{Appellant} to Col. 6, lines 57-59 of Dubois which teaches that his compositions can be used in the treatment of hirsutism, androgenic alopecia, and hyperpilosity, which are all conditions related to hair growth. Since Dubois teaches his compositions for topical application, it is respectfully pointed out that Dubois does teach applying his compositions to the hair, as topical treatment of hirsutism, androgenic alopecia, and hyperpilosity results in application of the composition to the area that needs to be treated, wherein these areas have hair. Additionally, it is respectfully pointed out that even if Dubois only applied these compositions to the scalp, the compositions would concurrently be applied to the hair, as it is impossible to apply a composition to the scalp without applying a composition to the hair. And as pointed out above, skin is a keratinous substance.

4/04
JW

~~Applicant~~^{Appellant} argues, "In contrast, Cretois treats "exoskeletal parts" rather than skin". This argument is not persuasive. It is respectfully pointed out that ~~Applicant~~^{Appellant} is improperly relying on a partial disclosure. It is respectfully pointed out that Cretois teaches, in the first paragraph of the patent, that "The present invention is directed to compositions intended for the treatment and the protection of keratinous exoskeletal parts, in particular the hair and the eyelashes". As pointed out above, the outermost layer of skin is a keratinous exoskeletal part.

Appellant argues, "Cretois and Dubois teach compositions directed to different purposes". This argument is not persuasive. The Examiner again respectfully points out that both Cretois and Dubois are directed to cosmetic compositions intended for topical application for the purpose of beautifying the outer appearance.

Appellant argues, "The proposed combination lacks motivation, because Dubois does not teach an 'antiseborrheic agent', and, "The Examiner has mischaracterized the teaching of

Dubois. . .Dubois thus does not state, as the Examiner alleges, that Dubois' compound of formula (I) is an antiseborrheic agent. Rather Dubois merely relates that the disclosed compositions can be used in the treatment of a diverse array of ailments, among them seborrhea". This argument is not persuasive. The Examiner respectfully points out that all of the compositions of Dubois are directed to compositions wherein compounds of formula (I) are the only active ingredients. Thus, in Col. 6, line 58, Dubois is teaching the compounds of formula (I) as a medicament for treating seborrhea.

Appellant argues, "Dubois clarifies that additional ingredients may be needed to treat the listed ailments". This argument is not persuasive and mischaracterizes the teachings referred to in Col. 6. Col. 6, lines 49-59 teach the compositions of the invention comprising compounds of formula I for treating various disorders. Col. 6, line 60-Col. 7, line 3, teach that additional ingredients can be added to the compositions to further enhance the active properties of formula I.

Appellant argues that there is lack of motivation to combine the references because "it is not taught or suggested how Dubois' vesicles in Cretois' compositions would reach skin intact". This argument is not persuasive. The Examiner respectfully points out that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. Additionally, there is no evidence that the vesicles would not reach the skin intact, especially since the compositions of Cretois require ceramides and the liposomes of Dubois require sphingolipids, wherein sphingolipids are ceramides.

Appellant argues, “sphingolipids react or interact with the vinylpyrrolidone polymers to cause this shape retaining effect, for example by immobilizing the sphingolipid on the hair. . Such immobilization is inconsistent with the therapeutic delivery required by Dubois”. This argument is not persuasive. As previously pointed out, application of a composition to the hair, concurrently results in application of a composition to the scalp. While the composition may have one therapeutic mode to effecting the hair, it can have another therapeutic mode of affecting the scalp. Again, it is pointed out that Cretois teach the addition of antisebborehic agents in their composition, wherein seborrhoeic is an affliction of the skin and not the hair. Thus, Cretois obviously is directed toward the keratinous skin cells surrounding and of the hair.

Appellant argues, “Lai does not teach combining captopil and minoxidil, since Lai requires a nitric oxide scavenger”. This argument is not persuasive, as Lai is merely relied upon to teach the combinability of captopril and minoxidil, wherein Cretois teaches minoxidil.

Appellant argues, “Lai does not teach treating alopecia, so much as reducing alopecia as an unwanted side effect”. This argument is not persuasive, as reducing alopecia is treating alopecia. The mode of obtaining the disorder is of no consequence.

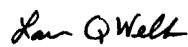
Appellant argues, “Ismail makes no connection between promoting blood circulation and treating alopecia”. This argument is not persuasive. As stated in the above rejection, Ismail exemplify a capsule for treating alopecia comprising pentoxifyllin.

Appellant argues, regarding WO ‘317, “The Examiner’s allegation that ‘specifically disclosed is 2,4-diamino-6-butoxy-3-sulfoxypyrimidiene [sic] hydroxide” is incorrect”. This argument is not persuasive. See page 12 of the instant specification, which specifically states that WO 92/21317 teaches 2,4-diamino-6-butyoxy-3-sulfoxypyrimidiene hydroxide.

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Appellant argues, "Claim 20 recites "2,6-diamino-4-piperidinopyridine. » The '701 PCT application teaches only 1,3,5-triazine compounds". This is correct. Claim 20 should have been rejected under WO 92/21317. For the above reasons, it is believed that the rejections should be sustained.

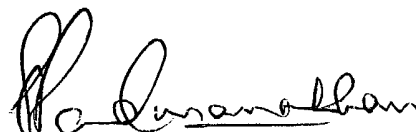
Respectfully submitted,


Lauren Q. Wells
April 8, 2004

Conferees

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